

REMARKS

Status Summary

Claims 21-32 are pending in the present application. Claims 21-32 presently stand rejected under the provisions of 35 U.S.C. §112, second paragraph. Claims 21-32 have also been rejected under the provisions of 35 U.S.C. §103(a) as being unpatentable over PCT Application No. WO 99/22228 to Karger et al. in view of the journal article of Rose & Jorgenson, *J. of Chromatography*, 438 (1988) 23-34 or U.S. Patent No. 4,911,807 to Burd.

Claims 21, 27-29, and 32 have been amended.

Claim Objection

Claims 28 and 29 are objected to by the Examiner upon the contention that these claims recite "*creating* a migratory field", whereas claim 21 upon which these claims depend recites "*generating* a migratory field". The objection has been obviated by amending claims 28 and 29 to substitute the term "generating" for "creating". Applicants note claim 27 has also been similarly amended.

Claim Rejections – 35 U.S.C. § 112

Claim 21 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. The Examiner contends: "interrupting the migratory field after collecting commences" as recited by Claim 21 conflicts with several recitations in the written description. Official Action at page 2.

Applicants respectfully disagree with the assertion advanced by the Examiner. However, in an effort to expedite prosecution of the subject application, applicants have amended Claim 1 to delete the term "commences". Therefore, amended Claim 21 now recites "interrupting the migratory field after the collecting". Support for this amendment can be found at page 7, lines 1-23. Applicants submit the amendment to Claim 1 obviates the rejection and respectfully request removal of this objection.

Claim 32 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicants regard as the invention. The Examiner argues that the phrase “composition of the separation pathway” is an incomprehensible limitation. Official Action at page 2. Applicants have amended Claim 32 to more particularly claim the recited subject matter. Amended Claim 32 now recites that the predetermined time interval is established based on “a mobility change of the analyte”. Thus, the time interval is established based on the mobility of the analyte. For example, where mobility of an analyte is half as fast, the time period is twice as long. Support for this amendment can be found beginning at page 14, line 24 through page 15, line 2 of the subject application. Applicants respectfully submit the amendment to Claim 32 obviates the rejection, and respectfully request withdrawal of the rejection.

#### Claim Rejection - 35 U.S.C. § 103

Claims 21-32 stand rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over PCT Application No. WO 99/22228 to Karger et al. (hereinafter referred to as “Karger et al.”) in view of the journal article of Rose & Jorgenson, *J. of Chromatography*, 438 (1988) 23-34 (hereinafter referred to as “Rose & Jorgenson”) or U.S. Patent No. 4,911,807 to Burd (hereinafter referred to as “Burd”).

The Examiner asserts that Karger et al. teaches all the elements of Claim 21 except for the “interrupting” step. Official Action at page 3. The Examiner further asserts that both Rose & Jorgenson and Burd teach interrupting the migratory field during a preparative capillary electrophoretic process. Official Action at page 4. The Examiner asserts that it would have been obvious at the time of the invention for one of ordinary skill in the art to have altered the teachings of Karger et al. with those of Rose & Jorgenson or Burd so as to provide a method inclusive of all the elements of Claim 21. The Examiner argues that one of ordinary skill in the art would have been motivated to make this combination because “this step will prevent the lost [sic] of a component of the sample during the transfer process.” Official Action at page 5.

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The position of the Examiner as summarized above with respect to Claim 21 is respectfully traversed as set forth hereinbelow.

Claim 21 recites a computer implemented method comprising applying a sample to an input of a separation pathway; generating a migratory field in this separation pathway; eluting an analyte of the sample from the separation pathway; collecting the analyte in a collection well without using a detector to analyze the analyte prior to collection; interrupting the migratory field after the collecting; and repeating the collecting and the interrupting, at a predetermined time interval, for a successive analyte and a successive collection well.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation; either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim elements. MPEP 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). Further, when considering whether a motivation to combine the references exists, the prior art references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed subject matter. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

Applicants respectfully submit that the combination of references, upon which the rejection of the claims relies, is improper in that the suggestion or motivation to combine the references is incorrect. As admitted by the Examiner, Karger et al. does not teach or suggest interrupting the migratory field. Assuming arguendo that Rose & Jorgenson or Burd teach that interrupting the migratory field is desirable in order to prevent loss of analyte when transferring a capillary between wells, Karger et al. teaches the exact opposite. Karger et al. repeatedly emphasizes the importance of maintaining a continuous migratory field through the capillary and goes to great

lengths to ensure this constancy. Karger et al. implements several mechanisms in this regard, including:

- (1) incorporating a liquid sheath or electrokinetic means around the capillary ends to maintain a conductive path between the capillary end and the collection well, even when moving the capillary between wells (Karger et al. at page 8, lines 2 through 13);
- (2) constructing the entire collection unit from an electrically conductive compound (e.g. agarose or polyacrylamide gels) to maintain conductivity (Karger et al. at page 8, lines 16 through 19);
- (3) immersing the collection unit in a solvent bath, which aids in maintaining electrical conductivity (Karger et al. at page 9, lines 31 through 34);
- (4) casting the collection unit with microchannels rather than wells, allowing consecutive microfluidic sample handling and eliminating the need to move the capillary from one well to the next (Karger et al. at page 9, lines 34 through 36 and Claim 31);
- (5) tilting capillary tubes at an angle for delivery of the analyte to the well to remove the need to lift capillaries up and away from the conductive wells, thereby interrupting the migratory field when moving between wells (Karger et al. at page 11, lines 1 through 18 and Figures 8A and 8B); and
- (6) developing “nozzle-shaped wells” having outwardly slanted walls so as to bring the top edges of individual wells close together, again removing the need to lift the capillary up and away from the conductive wells when moving between wells.

Therefore, considering the cited references in their entirety, including portions that would lead away from the claimed subject matter, one of ordinary skill in the art relying on the complete teachings of Karger et al. would certainly not be motivated to combine it with the teachings of either Rose & Jorgenson or Burd so as to practice the method of Claim 21, including interrupting the migratory field after the collecting, as

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Karger et al. repeatedly teaches against interrupting the field and goes to great lengths to achieve a continuous field.

Since all the elements of Claim 21 are neither taught nor suggested by Karger et al., Rose & Jorgenson or Burd, and when considering the teachings of the references as a whole, no proper motivation for combining the references exists, it is respectfully submitted that Claim 21 is patentably distinguished over the cited combination. Applicants therefore respectfully request withdrawal of the rejection of Claim 21 based on Karger et al. in view of Rose & Jorgenson or Burd. Allowance of Claim 21 is also respectfully required.

As Claims 22-32 either directly or indirectly from Claim 21, and the cited references do not teach or suggest all the elements of Claim 21 for the reasons stated above, the cited references therefore do not teach or suggest all the elements of these dependent claims either. Applicants therefore respectfully request withdrawal of the rejection of Claims 22-32 based on Karger et al. in view of Rose & Jorgenson or Burd. Allowance of Claims 22-32 is also respectfully requested.

### CONCLUSION

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

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DEPOSIT ACCOUNT

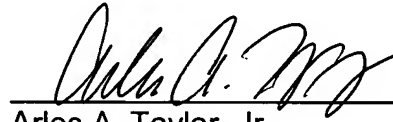
The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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Date: 04/28/2004

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